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MD6030170-956733
510(k) File Number: K070842

510(k) Summary (amended)

The Ulceloocin™ Oral Ulcer Patch

The following represents the summary for premarket notification of the Ulceloocin™ Oral Ulcer Patch, a product to be marketed by Sunshine International Group, Inc., located at 1333 Broadway, Suite 1222, New York, NY 10018, (212)268-7771.

CONTACT PERSON: Liping He
Vice President
(212) 268-7771

DATE OF SUMMRY: February 24, 2007

DEVICE NAME:

Proprietary Name: Ulceloocin™ Oral Ulcer Patch

Common Name: Oral Wound Dressing

Classification Name: **Unclassified.**

PREDICATE DEVICE: The SaliCept™ Oral Patch K012126 (Carrington Laboratories, Inc.)

DEVICE DESCRIPTION:
Ulceloocin™ Oral Ulcer Patch is a vacuum-dried gel that contains hydrogel with calcium and phosphorus. It does not contain any biological additives or drugs. It is a round, white to off-white thin patch. Ulceloocin™ Oral Ulcer patch is packaged in blister cards of two patches per card, three blister cards per carton, for a total of 6 patches per carton. Each patch is approximately 1 cm in diameter and 0.3 mm thick.

INTENDED USE:
Ulceloocin™ Oral Ulcer Patch is intended for use as an oral wound dressing to protect ulcer tissue by forming a physical barrier on the wound tissue to avoid further irritation and thus to relieve pain. It is indicated for use with all types of ulcers and small wounds of the oral mucosa including canker sores, aphthous ulcers, and injuries such as traumatic ulcers caused by self-biting, braces, and ill-fitting dentures.

CLAIMS:

Ulceloocin™ Oral Ulcer Patch relieves pain by adhering to and protecting affected tissues from further irritation. It is safe if swallowed.

TECHNOLOGICAL CHARACTERISTICS:
Ulceloocin™ Oral Ulcer Patch is a vacuum-dried hydrogel that adheres to oral mucosa. It is slowly reverts to a soft and gel-type thin sheet in the oral environment while it adheres to and protects affected tissue as a physical barrier to reduce irritation and pain.

NON-CLINICAL DATA:
In vitro study was conducted for cytotoxicity test of Ulceloocin™ Oral Ulcer Patch. Animal biocompatibility studies were conducted for skin irritation test and hypersensitivity test of Ulceloocin™ Oral Ulcer Patch. The studies indicated that Ulceloocin™ Oral Ulcer Patch does not have cytotoxic effect on human cells, and does not cause any irritation or hypersensitivity to the animals tested. The safety and biocompatibiltiy Ulceloocin™ Oral Ulcer Patch are confirmed by both in vitro and animal biocompatibility studies.

CLINICAL DATA:
Multi-centered clinical trials of Ulceloocin™ Oral Ulcer Patch were conducted in two hospitals as Trial 1 and Trial 2 on a total of 95 patients with oral mucosal ulcers according to the current good clinical practice procedures and IRB approval. Forty-five patients were studied in Trial 1 and fifty patients were studied in Trial 2. In these two trials, a total of fifty patients were treated with Ulceloocin™ Oral Ulcer Patch four times a day, before the meals and bedtime, as the study group; and a total of forty-five patients with the same lesions were not treated as the control group.

Effect on pain relief was mainly determined by measuring the pain index at the time of eating food during the time course of trial. Patients in both study and control groups had a starting pain index of 7.33 - 7.37 (Trial 1) and 7.30 - 7.40 (Trial 2) at the time of being enrolled into the study. At the 4th day of study, study group showed a significant reduction to 2.26 ± 2.20 (Trial 1) and 2.24 ± 2.40 (Trial 2) compared to a pain index of 5.31 ± 2.42 (Trial 1) and 6.10 ± 2.33 (Trial 2) in control group. At 7th day, study group showed a pain index of 0.20 ± 0.72 (Trial 1) and 0.80 ± 1.80 (Trial 2) compared to a pain index of 1.53 ± 1.72 (Trial 1) and 2.31 ± 1.82 (Trial 2) in control group. Ulceloocin™ Oral Ulcer Patch demonstrated a significant effect on reducing the pain caused by oral mucosal ulcers ($P < 0.01$) in both trials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 7 2007

Mr. Liping He
Vice President
Sunshine International Group, Incorporated
1333 Broadway, Suite 1222
New York, New York 10018

Re: K070842
Trade/Device Name: Ulceloocin™ Oral Ulcer Patch
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: MGQ
Dated: May 16, 2007
Received: May 22, 2007

Dear Mr. Fisher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K070842

Statement of Indication for Use

510(k) Number (if known):_____

Device Name: Ulceloocin™ Oral Ulcer Patch

Indications for Use:

Ulceloocin™ Oral Ulcer Patch is intended for use as an oral wound dressing to protect ulcer tissue by forming a physical barrier on the wound tissue to avoid further irritation and thus to relieve pain. It is indicated for use with all types of ulcers and small wounds of the oral mucosa including canker sores, aphthous ulcers, and injuries such as traumatic ulcers caused by self-biting, braces, and ill-fitting dentures.

Prescription Use____ OR Over-The-Counter-Use__X__

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number K070842